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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,250	07/23/2003	Yoram Wasserman	02,647-664	9299

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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,250

Applicant(s)

WASSERMAN, YORAM

Examiner

Matthew J. Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,10-13,16,17,19,23,25,28,32,34-42 and 49-59 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,10-13,16,17,19,23,25,28,32,34-42 and 49-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/23/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-5, 10, 16-17, 23, 32, 34-38, 50-53, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,825,672 to Brudnoy. Brudnoy teaches a method and apparatus for processing a measured signal that includes the steps of determining an upper envelope, determining a lower envelope, and analyzing the upper and lower envelope. (column 7, line 11 to column 8, line 28 of Brudnoy). In regard to claims 4 and 57, the median is determined. (column 8, lines 10-28 of Brudnoy). In regard to claims 5, 35, and 51, a physiological, substantially periodic signal is contemplated. (column 1, lines 26-40 of Brudnoy). In regard to claims 10, 16, 38, and 53, application of an external field is contemplated. (column 1, lines 26-40 of Brudnoy). In regard to claim 17, frequency filtering and sampling are contemplated. (column 3, lines 26-51 of Brudnoy). In regard to claims 23, 32, and 50, an apparatus is contemplated. (Fig. 1 of Brudnoy).

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3. Claims 1, 3-7, 10-12, 16-17, 23, 25, 32, 34-42, and 50-59 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,216,598 to Branstetter et al. (Branstetter) (cited by Applicant). Branstetter teaches a method and apparatus for processing a measured signal that includes the steps of determining an upper envelope, determining a lower envelope, and analyzing the envelopes to extract the signal component from the measured signal. (column 4, lines 50-56 of Branstetter). In regard to claim 3, the last four pulse amplitudes are used to calculate the minimum and maximum pulse amplitude. (column 5, lines 3-13 of Branstetter). In regard to claim 4, a median of half of the sum of the upper and lower values is determined. (column 6, lines 45-53 of Branstetter). In regard to claims 5-7, oxyhemoglobin saturation level is determined. (column 5, lines 26-58 of Branstetter). In regard to claims 10-12, 16, 25, 39-42, and 53-56, the measured signal comes from a pulse oximeter, which means application of an external field in the form of light and detection of the light are contemplated. (column 5, line 26 to column 6, line 63 of Branstetter). In regard to claims 23, 32, and 50, an apparatus is contemplated. (Fig. 1 and column 3, lines 51-66 of Branstetter).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13, 19, 28, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,216,598 to Branstetter et al. (Branstetter) (cited by Applicant) in view of U.S. Patent 5,797,840 to Akselrod et al. (Akselrod) (cited by Applicant). Branstetter teaches a method and apparatus for processing a measured signal that includes the steps of determining an upper envelope, determining a lower envelope, and analyzing the envelopes to extract the signal component from the measured signal. (column 4, lines 50-56 of Branstetter). Branstetter does not teach the determination of the heart rate using a derivative of Gaussian parameters or spectral filtering. Akselrod teaches using a plethysmograph for determining heart rate. A derivative of a Gaussian window is used in the processing method and a spectral transform apparatus is used in conjunction with the window. (column 4, lines 1-22 of Akselrod). It is well known in the art to provide the heart rate while monitoring a patient's condition since a more complete diagnostic picture will result. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Branstetter with the invention of determining the heart rate as disclosed by Akselrod since it would result in a more complete diagnostic picture will result.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 3-7, 10-13, 19, 23, 25, 28, 34-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 13, 15-16, 18-26 of U.S. Patent No. 6,658,277 to Wasserman. Although the conflicting claims are not identical, they are not patentably distinct from each other. In regard to claim 1 of the present application, claim 1 of Wasserman claims a "method for processing a measured signal to extract a signal component and suppress a noise component of the measured signal, wherein the signal component is a substantially periodic signal characterized by a substantially well-defined peak-to-peak intensity value, the method comprising the steps of: (i) determining upper and lower envelopes of the measured signal; and (ii) analyzing the upper and lower envelope values to extract the signal component from the measured signal". Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of Wasserman claims a method which is narrower in scope than the present application. Claim 1 of Wasserman meets all the limitations set out in claim 1 of the present application and it would be obvious that the method of claim 1 of the present application is actually the method of claim 1 of Wasserman.

In regard to claim 3 of the present application, claim 2 of Wasserman claims “wherein the step of analyzing the upper and lower envelope values includes the step of determining a median of the upper envelope values, as a constant value in the signal component”. In regard to claim 4 of the present application, claim 3 of Wasserman claims “wherein the step of analyzing the upper and lower envelope values includes the step of determining a median of the half of the sum of the upper and lower envelope values, as a constant value in the signal component”. In regard to claim 5 of the present application, claim 4 of Wasserman claims “wherein the measured signal is a physiological signal”. In regard to claim 6 of the present application, claim 5 of Wasserman claims “wherein the signal component is pulsatile blood-related signal”, which inherently is a physiological signal. In regard to claim 7 of the present application, claim 6 of Wasserman claims “wherein the pulsatile blood-related signal is indicative of oxyhemoglobin saturation level”. In regard to claim 10 of the present application, claim 7 of Wasserman claims “wherein the measured signal is a response of a sample to the application of an external field”. In regard to claim 11 of the present application, claim 8 of Wasserman claims “wherein the measured signal is a light response of the sample to incident light”. In regard to claim 12 of the present application, claim 9 of Wasserman claims “wherein the sample [is] biological”. In regard to claim 13 of the present application, claim 10 of Wasserman claims “for use with a measurement device for non-invasive measurements of patient's blood and heart conditions, the signal component being a pulsatile blood-related signal and containing a signal component characterized by a specific asymmetric shape, the method further

comprising the steps of: defining a kernel function being a derivative of a Gaussian with parameters matching the characteristics of the signal component with the asymmetric shape; and applying spectral filtering to the measured signal with the kernel function, thereby enhancing the signal component characterized by the specific asymmetric shape relative to a noise component in the filtered signal, to thereby enable further processing of the enhanced pulse signal to determine the heart rate”.

In regard to claim 19 of the present application, claim 13 of Wasserman claims a “method for processing a measured signal to extract a signal component” which includes the limitations: “wherein the signal component is a substantially periodic signal characterized by a substantially well-defined peak-to-peak intensity value” (the first signal component) and “a signal component characterized by a specific asymmetric shape” (the second signal component). The method is for processing a measured signal and “suppress a noise component of the measured signal”; the method “comprising the steps of: determining upper and lower envelopes of the measured signal; analyzing the upper and lower envelope values to extract the signal component from the measured signal; defining a kernel function being a derivative of a Gaussian with parameters matching the characteristics of the signal component with the asymmetric shape; and applying spectral filtering to the measured signal with the kernel function, thereby enhancing the signal component characterized by the specific asymmetric shape relative to a noise component in the filtered signal”. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of Wasserman claims a method which is narrower in scope than the

present application. Claim 13 of Wasserman meets all the limitations set out in claim 19 of the present application and it would be obvious that the method of claim 19 of the present application is actually the method of claim 13 of Wasserman.

In regard to claim 23 of the present application, claim 15 of Wasserman includes a “control unit connectable to the measurement device for receiving and processing the measured signal, the control unit comprising a data processing and analyzing utility preprogrammed to determine upper and lower envelopes of the measured signal, and analyze the upper and lower envelope values to extract said pulsatile blood-related signal component from a noise component in the measured signal”. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 of Wasserman claims an apparatus which is narrower in scope than the present application. Claim 15 of Wasserman meets all the limitations set out in claim 23 of the present application and it would be obvious that the apparatus of claim 23 of the present application is actually the apparatus of claim 15 of Wasserman.

In regard to claim 25 of the present application, claim 15 of Wasserman claims a “pulse oximeter comprising: (a) a measurement device operable to illuminate a measurement location with incident light of predetermined frequencies, detect a light response of the measurement location to said incident light, and generate a measured signal indicative thereof including a signal component representative of a pulsatile blood-related signal; and (b) a control unit connectable to the measurement device for receiving and processing the measured signal, the control unit comprising a data processing and analyzing utility preprogrammed to determine upper and lower

envelopes of the measured signal, and analyze the upper and lower envelope values to extract said pulsatile blood-related signal component from a noise component in the measured signal". Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 of Wasserman claims an apparatus which is narrower in scope than the present application. Claim 15 of Wasserman meets all the limitations set out in claim 25 of the present application and it would be obvious that the apparatus of claim 25 of the present application is actually the apparatus of claim 15 of Wasserman.

In regard to claim 28 of the present application, claim 16 of Wasserman claims the "pulse oximeter...for determining a patient's heart rate, the measured signal comprising a blood-related signal component characterized by a specific asymmetric shape, the control unit being preprogrammed to process the measured signal by filtering it with a predefined kernel function being a derivative of a Gaussian with parameters matching the characteristics of said signal component, thereby enhancing said signal component characterized by the specific asymmetric shape relative to a noise component in the filtered measured signal".

In regard to claim 34 of the present application, claim 18 of Wasserman claims a "method for determining a parameter of a signal, comprising: (i) determining upper and lower envelopes of the signal, and (ii) analyzing the upper and lower envelopes to extract a signal component of the signal; and, (iii) determining the parameter of the signal as a function of the signal component". Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 18 of

Wasserman claims a method which is narrower in scope than the present application.

Claim 18 of Wasserman meets all the limitations set out in claim 34 of the present application and it would be obvious that the method of claim 34 of the present application is actually the method of claim 18 of Wasserman.

In regard to claim 35 of the present application, claim 19 of Wasserman claims "wherein the signal component is substantially periodic". In regard to claim 36 of the present application, claim 20 of Wasserman claims "wherein the signal component has a substantially defined peak-to-peak intensity value". In regard to claim 37 of the present application, claim 21 of Wasserman claims a "wherein the step of analyzing the upper and lower envelopes includes the step of suppressing noise". In regard to claim 38 of the present application, claim 22 of Wasserman claims "the steps of applying an external field to a sample and sensing the signal, wherein the signal is a response of the sample to the external field". In regard to claim 39 of the present application, claim 23 of Wasserman claims "the steps of applying incident radiation to a sample and sensing the signal, where the signal is a response of the sample to the incident radiation". In regard to claim 40 of the present application, claim 24 of Wasserman claims "wherein the parameter of the signal corresponds to a physiological parameter of the sample". In regard to claim 41 of the present application, claim 25 of Wasserman claims "wherein the physiological parameter is pulsatile blood-related". In regard to claim 42 of the present application, claim 26 of Wasserman claims the "physiological parameter is oxyhemoglobin saturation".

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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